

CLAIMS

1. A method for the *in vitro* differentiation between systemic inflammatory non-infectious conditions and systemic inflammatory infectious conditions, thereby characterized, that it includes the following steps:

- a) isolation of sample RNA from a biological sample;
- b) marking the sample RNA and/or at least one DNA, which has a gene activity that is specific for distinguishing between SIRS and sepsis and/or is a specific gene or gene fragment, with a detectable marker;
- c) bringing the sample RNA in contact with the DNA in hybridization conditions;
- d) bringing control RNA in contact with at least one DNA, under hybridization condition, said DNA representing a gene or gene fragment that is specific for distinguishing between SIRS and sepsis;
- e) quantitatively measuring the marking signals of the hybridized sample A and control RNA; and
- f) comparing the quantitative data of the marking signals in order to make a determination as to whether genes or gene fragments that are specific for distinguishing between SIRS and sepsis are expressed more prominently or less prominently in the sample than in the control RNA.

2. A process according to claim 1, thereby characterized, that prior to measurement of the sample-RNA the control-RNA is hybridized with the DNA and the marker signal of the control-RNA/DNA-complex is determined and is optionally recorded in the form of a calibration curve or table.

3. A process according to claim 2, thereby characterized, that unchanged gene from the sample and/or control-RNA was used as the reference gene for quantification.

4. A process according to claims 1 through 3, thereby characterized, that mRNA was used as the sample-RNA.

5. A process according to claims 1 through 4, thereby characterized, that the DNA is provided in predetermined locations, in particular immobilized upon a carrier in the form of a microarray.

6. A process according to claims 1 through 5, thereby characterized, that the process is employed for differential diagnostic early recognition, for control of the clinical treatment, for individual risk assessment for patients for evaluation of the probability of response to the specific treatment as well as for post-mortem diagnosis for distinguishing between SRIS and sepsis.

7. A process according to claims 1 through 6, thereby characterized, that the sample is selected from: body fluids, in particular blood, serum, urine peritoneal fluid, seminal fluid, saliva, tissue fluids; cell contents or a mixture thereof.

8. A process according to one of claims 1 through 7, thereby characterized, that cell samples are in certain cases subject to lysis treatment in order to release cellular contents.

9. A process according one of claims 1 through 8, thereby characterized, that the sample is a biological sample of human origin.

10. A process according to one of claims 1 through 9, thereby characterized, that for distinction between SIRS and sepsis, specific gene and/or gene fragments are selected from the group consisting of SEQ-ID No. 1 through SEQ-ID No. 91, as well as gene fragments thereof with at least 5-2000, preferably 20-200, more preferably 20-80 nucleotides.

11. A process according to one of claims 1 through 10, thereby characterized, that at least 2-100 cDNAs are employed.

12. A process according to one of claims 1 through 11, thereby characterized, that at least 200 cDNAs are employed.

13. A process according to one of claims 1 through 12, thereby characterized, that at least 200-500 cDNAs are employed.

14. A process according to one of claims 1 through 13, thereby characterized, that at least 500-1000 cDNAs are employed.

15. A process according to one of claims 1 through 14, thereby characterized, that at least 1000-2000 cDNAs are employed.

16. A process according to one of claims 1 through 15, thereby characterized, that the genes or gene fragments and/or sequences derived from their RNA listed in claim 10 are replaced by synthetic analogs, aptamers as well as peptido-nucleic acids.
17. A process according to claim 16, thereby characterized, that the synthetic analogs of the genes include 5-100, in particular approximately 70 base pairs.
18. A process according to one of claims 1 through 17, thereby characterized, that the detectable markers are a radioactive marker, in particular ^{32}P , ^{14}C , ^{125}I , ^{155}Eu , ^{33}P , or ^3H .
19. A process according to one of claims 1 through 17, thereby characterized, that as the detectable markers a non-radioactive marker, in particular a color or fluorescence marker, an enzyme marker or an immuno marker and/or quantum dots or an electric measurable signal in particular potentiometric and/or conductivity and/or capacitance change upon hybridization, is employed.
20. A process according to one of claims 1 through 19, thereby characterized, that the sample-RNA and the control-RNA and/or enzymatic or chemical derivatives carry the same carrier markers.
21. A process according to one of claims 1 through 19, thereby characterized, that the sample-RNA and the control-RNA and/or enzymatic or chemical derivatives carry different markers.
22. A process according to one of claims 1 through 19, thereby characterized, that the immobilized or non-immobilized samples carry a marker.
23. A process according to one of claims 1 through 22, thereby characterized, that the DNA sample is immobilized on glass or plastic.
24. A process according to one of claims 1 through 23, thereby characterized, that the individual DNA molecules are immobilized by a covalent bonding to the carrier material.
25. A process according to one of claims 1 through 24, thereby characterized, that the individual DNA molecules are immobilized by electrostatic and/or dipol-dipol and/or hydrophobic interaction and/or hydrogen bridges to the carrier materials.
26. Use of recombinant or synthetic produced nucleic acid sequences having specificity for distinguishing between SIRS and sepsis, or partial sequences individually or in subsets, as

calibrators in sepsis-assays and/or for evaluation of the effectivity or toxicity in a screening for active substances and/or for production of therapeutics and of substances and substance mixtures, which can be used as therapeutics, for prevention and treatment between SIRS and sepsis.

27. Use of RNA of the gene and/or gene fragment according to claim 10 for obtaining qualitative information regarding the gene activity by hybridization-independent processes, in particular enzymatic and/or chemical hydrolysis and/or amplification processes, preferably PCR, subsequent quantification of the nucleic acids and/or of derivatives and/or fragments thereof.

28. Use of gene activities of genes and/or gene fragments according to claim 10 which are specific for SIRS or sepsis for active substance screening in model organisms.

29. Use of gene activities according to claims 1 through 25 which on the cellular level are modulated by gene activities of the genes and/or gene fragments according to claim 10.

30. Use of genes and/or gene fragments according to claim 10 for obtaining information regarding a sepsis or SIRS condition for electronic further processing.

31. Use of gene activity data for the production of software for diagnostic purposes and/or patient data management systems.

32. Use of gene activity data for provision of experimental systems for modeling of cellular signal transmitter pathways.